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U.S. Army Center for Health Promotion and Preventive Maintenance (USACH PPM)
Strategic Initiatives Office (SIO), Quality Assurance Team (QAT)

STANDING OPERATING PROCEDURE
FOR
QUALITY ASSURANCE REPONSIBILITIES

Preparer — 03 JAN 20 1 Date

Supervisor Approval — 1/4/2001 Date

Annual Review

Preparer	03JAN02 Date Due	____ Date C	____ mp.
Supervisor	03JAN02 Date Due	____ Date	____ Comp.
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Disclaimer: This Standing Operating Procedure has been prepared for the sole u e of the U. S. Army Center For Health Promotion and Preventive Medicine (USACHPP I) and may not be specifically applicable to the activities of other organizations.

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I. PURPOSE: This standing operating procedure (SOP) describes the responsibilities of the Strategic Initiatives Office with respect to GLP compliance of Department of Toxicology Operations (DTOX) studies as well as all analytical support and contract laboratories.

II. APLPLICABILITY: It is the policy of the USACHPPM that every effort is made to assure that all studies undertaken by DTOX and the reports of such studies are of the highest possible quality and adhere to the best standards of professional scientific endeavor. It is the further the policy of USACHPPM that the regulations of the Food and Drug Administration (FDA) (21 CFR Part 58), the Environmental Protection Agency's (EPA) (40 CFR Part 160) and the Environmental Protection Agency's (EPA) (40 CFR Part 792) for Good Laboratory Practices (GLP) in Nonclinical Laboratories be followed in every particular for all (DTOX) studies. To assist in implementation of this policy, a Quality Assurance Team (QAT) has been established as an integral and permanent organizational unit of USACHPPM.

III. DEFINITIONS: None.

IV. QUALITY CONTROL: None.

V. PROCEDURE: The objective of the QAT will be to insure compliance with the experimental protocols, provide a basis for the continuous improvement of DTOX and DLS technical staff, and provide a continuous conformance to GLP regulations. The responsibilities of the QAT are to:

A. Maintain a copy of the Facility Master Schedule of all nonclinical studies conducted in DTOX.

B. Maintain copies of all protocols, Standard Operating Procedures (SOPs) and technical manuals pertaining to all nonclinical studies conducted in DTOX.

C. Review all protocols prior to study initiation to assure compliance with SOPs and with the appropriate government regulations.

D. Assure that no deviations from approved protocols or SOPs are made without prior written authorization.

E. Inspect phases of each study periodically to detect any deviations in the experimental procedures dictated by the protocol and/or SOPs and maintain properly signed and dated records of each assessment.

F. Review all experimental data of a study periodically to assure timely performance of data documentation and adequacy of record keeping practices.

G. Review the final report of each study conducted in DTOX to assure that the report accurately describes the experimental methods, raw data, observations and SOPs pertaining to the study and that the reported results are an accurate reflection of the study data.

H. Provide the Study Director and Laboratory Management with a written report of any problems or deficiencies found during inspections, raw data audits or report reviews for information and appropriate corrective action.

I. Prepare and sign a statement, to be included in the final report, specifying the dates inspections or audits were made and findings reported to the Study Director and Laboratory Management.

J. Perform general laboratory inspections for overall cleanliness, orderliness and safety and to confirm adherence to facility SOPs and equipment maintenance/calibration schedules.

K. Provide Laboratory Management with written summaries of all inspections and audits performed which include problems encountered and corrective actions taken.

L. Attend Institutional Animal Care and Use Committee (ACUC) meetings as a non-voting member.

M. Attend Quality Operation Management Board (QOMB) meetings as a voting member.

N. Attend Chemical Hygiene Committee (CHC) meetings as a voting member.

O. Perform and/or coordinate In-house ISO/IEC Guide 25 (A2LA criteria) audits as required.

IV. SAFETY CONSIDERATION: Compliance with all division and branch safety procedures, SOPs and the DLS Chemical Hygiene Plan requirements is mandatory.

V. REFERENCES:

A. USFDA Federal Food, Drug and Cosmetic Act (FFDCA); 21 CFR 58 (1979), latest edition.

B. USEPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); 40 CFR 160 (1984), latest edition.

C. USEPA Toxic Substances Control Act (TSCA); 40 CFR 792 (1983), latest edition.